IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

RITE AID CORPORATION, RITE AID HDQTRS. CORP., JCG (PJC) USA, LLC, MAXI DRUG, INC. d/b/a BROOKS PHARMACY, and ECKERD CORPORATION, Plaintiffs, vs. ABBOTT LABORATORIES, ABBVIE INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA WOMEN'S HEALTH, INC. F/K/A DURAMED PHARMACEUTICALS INC., and DURAMED PHARMACEUTICALS SALES CORP. Defendants.	Civil Action No.: JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Rite Aid Corporation, Rite Aid Hdqtrs. Corp., JCG (PJC) USA, LLC, Maxi Drug, Inc. d/b/a Brooks Pharmacy, and Eckerd Corporation (collectively "Plaintiffs"), file this Complaint under the antitrust laws of the United States against Defendants Abbott Laboratories, AbbVie Inc. ("AbbVie"), (together with Abbott Laboratories, "Abbott"), Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries, Ltd., and Teva Women's Health, Inc. f/k/a Duramed Pharmaceuticals Inc. ("Duramed"), and Duramed Pharmaceuticals Sales Corp. ("DPSC") (collectively "Teva"), and Barr Pharmaceuticals Inc. ("Barr") (collectively "Defendants"). For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful delay of generic Niaspan, a branded extended-release niacin product used to treat lipid disorders. Niacin is a form of vitamin B, and niacin pills have been used since the 1930s. Niaspan has been sold as a prescription drug since 1997, first by Kos Pharmaceuticals, Inc. ("Kos") and later by Abbott and AbbVie, following various corporate mergers and restructuring. Although the first of several would-be generic competitors began applying to market generic extended-release niacin in October 2001, no generic competitor entered the market until September 2013, nearly twelve years later.

2. The unlawful scheme described below caused that delay. In 2005, Kos colluded with would-be generic competitor Barr to illegally delay generic entry by paying Barr (a) not to enter the market until September 20, 2013, and (b) to drop challenges to Kos's patents that ostensibly covered Niaspan. Kos's successors, Abbott and AbbVie, and Barr's successor, Teva, continued this illegal collusion and unreasonable restraint of trade at the expense of Niaspan purchasers. Every month of delay of generic competition allowed Kos and its successors to preserve millions of dollars in monopoly profits from the sale of Niaspan and allowed Barr and its successor to share in those profits by pocketing millions of dollars from Kos for agreeing to delay generic extended-release niacin.

3. Beginning in early 2002, after Barr became the first generic manufacturer to seek approval from the Food and Drug Administration ("FDA") to market generic extended-release niacin, Kos sued Barr, accusing it of infringing several patents ostensibly covering Niaspan. These lawsuits automatically triggered a thirty-month stay of FDA approval. As a result, regardless of the merits of the patent infringement case, the FDA could not grant final approval

to Barr to launch its generic product until March 31, 2005. Blocking Barr's launch of generic Niaspan also foreclosed all other generic manufacturers from launching since Barr was entitled to 180 days of market exclusivity as the first manufacturer to seek approval for generic extended-release niacin.

4. Between early 2002 and early 2005, while the thirty-month stay was in effect, Barr fought the patent infringement actions and prepared to bring its generic extended-release niacin to market to compete with Niaspan. In March 2005, Barr was ready to launch generic Niaspan. It had received tentative approval from the FDA for three different strengths of extended-release niacin in mid-2003, and final approval was subject only to expiration of the thirty-month stay. In the months and weeks leading up to March 2005, Barr began accumulating inventory that it would need to fill orders for its product as soon as launch occurred. All Barr needed was final FDA approval.

5. During this time, the patent litigation continued. Launching before the conclusion of patent litigation potentially creates risk for a generic manufacturer such as Barr; if the court finds the relevant patent(s) valid, enforceable, and infringed, the generic company may face substantial financial exposure from selling an infringing product. But Barr was so certain that it would prevail that it planned to launch its generic extended-release niacin as soon as the FDA gave the final green light, notwithstanding the pending patent litigation.

6. Barr expected to receive the green light from the FDA in April 2005. And Barr's expectation was correct: on April 26, 2005, the FDA granted final approval for three strengths of Barr's generic extended-release niacin.

7. Barr was prepared to begin selling generic Niaspan, and competition would have commenced, but for one thing. Not coincidently, a few days earlier Kos and Barr colluded to

delay generic competition and maintain Kos's monopoly at the expense of Niaspan purchasers. Rather than face one or more less expensive generics in the market and suffer the reduction in Niaspan sales and profits such competition would have caused, Kos paid Barr to stay off the market for eight years. Kos's payments to Barr took two primary forms: cash and an agreement not to launch a competing "authorized generic" version of Niaspan when Barr eventually launched its generic in 2013. Barr accepted the payments, worth hundreds of millions of dollars, and agreed not to compete.

8. The scheme worked exactly as planned. Neither Barr nor any other generic competitor sold generic extended-release niacin until on or about September 20, 2013, far later than would have occurred absent Defendants' unlawful agreement.

9. Had Barr (or its successor, Teva) launched a generic version of Niaspan at any time before September 20, 2013, extended-release niacin would have been sold at lower prices than the prices at which Kos/Abbott/AbbVie actually sold branded Niaspan, and Plaintiffs would have paid lower prices than they actually paid.

10. Had Barr launched earlier than September 20, 2013, whether at-risk, via a payment-free settlement with an earlier entry date, or after prevailing in the patent litigation, other generic manufacturers with applications for approval to sell generic equivalents of Niaspan would have been permitted to launch their own products following the lapse of Barr's 180-day exclusivity period. By delaying Barr's launch until September 20, 2013, Kos and Barr sought to prevent, and have succeeded in preventing, other generic competitors from launching until 2014.

11. Plaintiffs are direct purchasers or assignees of direct purchasers of Niaspan and are included in the proposed class definition in actions pending in this Court as part of *In re Niaspan Antitrust Litigation*, MDL Docket No. 2460. The limitations period applicable to Plaintiffs'

claims has been tolled since the filing of the first class action on behalf of direct purchasers of Niaspan.

II. PARTIES

12. Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp., with a principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011, are corporations organized and existing under the laws of the State of Delaware (collectively "Rite Aid"). Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public through nearly 4,600 drugstores operated by its affiliates. Rite Aid brings this action on its own behalf and as the assignee of McKesson Corporation, which during the relevant period purchased Niaspan directly from Abbott for resale to Rite Aid and which has assigned its claims arising out of those purchases to Rite Aid.

13. Plaintiff JCG (PJC) USA, LLC ("JCG USA") is a Delaware limited liability corporation with a principal place of business in Camp Hill, Pennsylvania. On June 4, 2007, JCG USA became a wholly-owned subsidiary of Rite Aid Corporation. JCG USA is the parent corporation of Plaintiffs Maxi Drug, Inc. d/b/a Brooks Pharmacy ("Brooks") and Eckerd Corporation ("Eckerd"), both of which are Delaware corporations. JCG USA, Brooks and Eckerd hereafter are collectively referred to as "Brooks/Eckerd." Brooks/Eckerd purchases substantial quantities of pharmaceutical products and other goods for resale to the public through its retail stores. Brooks/Eckerd brings this action on its own behalf and as the assignee of McKesson Corporation, which during the relevant period purchased Niaspan directly from Abbott for resale to Brooks/Eckerd and which has assigned its claims arising out of those purchases to Brooks/Eckerd.

14. Defendant Abbott Laboratories is an Illinois corporation, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott purchased Kos

Pharmaceuticals, Inc. in 2006. On or about on January 1, 2013, Abbott spun off most of its pharmaceutical operations to AbbVie Inc.

15. Defendant AbbVie Inc. is a Delaware corporation, with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois.

16. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454.

17. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation, with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, Israel. Teva is a leading manufacturer of generic drugs and one of the largest sellers of generic drugs in the United States.

18. Prior to its acquisition by Teva in December 2008, Defendant Barr Pharmaceuticals Inc. was a Delaware corporation, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. In December 2008, Barr Pharmaceuticals Inc. became a wholly-owned subsidiary of Teva.

19. Defendant Duramed Pharmaceuticals Inc. is a Delaware corporation, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In 2008, when Teva purchased Barr, Duramed became a subsidiary of Teva. Duramed, along with Duramed Pharmaceuticals Sales Corp., is now known as Teva Women's Health, Inc.

20. Defendant Duramed Pharmaceuticals Sales Corp. is a Delaware corporation, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, DPSC was a subsidiary of Barr. In 2008, when Teva purchased Barr, DPSC became a subsidiary of Teva.

21. Kos Pharmaceuticals, Inc. ("Kos") and its wholly-owned subsidiary Kos Life Sciences, Inc. were among the initiators of the unlawful scheme described in this complaint. Kos was a Florida corporation, with its principal place of business at 1 Cedar Brook Drive, Cranbury, New Jersey. In 2006, Kos and Kos Life Sciences, Inc. were acquired by and merged into Abbott, which became the successor to all of their unlawful conduct described in this Complaint.

22. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

23. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover threefold damages, injunctive relief, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiffs and/or their assignors resulting from Defendants' unlawful foreclosure of the United States market for extended-release niacin. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

24. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, as well as 28 U.S.C. §1391(b) and (c) and 28 U.S.C. § 1407(a).

IV. OPERATIVE FACTS

A. Characteristics of the Prescription Pharmaceutical Marketplace

25. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person both pays for and chooses the products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to compete by lowering product prices.

26. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain pharmaceutical products, including Niaspan, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

27. Abbott and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

28. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand -- the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

29. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. *Id.* at §§ 355(a) & (b).

30. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If a brand manufacturer obtains a patent after FDA approval of an NDA, it must subsequently list it in the Orange Book within thirty days of the patent's issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

31. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

32. The Hatch-Waxman Amendments (also "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must only show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug -- that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

33. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug

would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

34. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

35. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total prescription drug revenue had soared to $300 billion.

D. Paragraph IV Certifications

36. Under the Hatch-Waxman Act, a manufacturer must make one of four certifications to obtain FDA approval of an ANDA:

a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

37. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent

infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

38. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. When a single generic enters the market, its price, while lower than the branded price, is typically higher than it would be if there were multiple generic competitors on the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at a higher duopoly price for six months may be worth hundreds of millions of dollars.

39. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files

an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition -- as opposed to enforcing a valid patent that is actually infringed by the generic -- is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of drug products studied by the FTC.

40. The first generic applicant can help the brand manufacturer "game the system" because by delaying its own market entry, it can also delay the market entry of all other generic manufacturers. By agreeing not to begin marketing its generic drug, the first generic applicant delays the start of its 180-day period of generic market exclusivity thereby preventing any subsequent generic applicants from coming to market, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity expires or is forfeited.

E. Benefits of Generic Drugs

41. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus results in huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, one year after market entry, the generic version takes over 90% of the brand's unit

sales and sells for 15% of the price of the brand name product. As a result, competition from generic drugs is viewed by brand name drug companies such as Kos/Abbott/AbbVie as a grave threat to their bottom lines.

42. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists presented with a prescription for a brand name prescription drug liberally and substantially substitute a generic version when one is available. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

43. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices without losing sales. As a result, brand manufacturers, who are well aware of the effect of generics on brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the reverse payment agreement at issue here.

F. Authorized Generics

44. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period pursuant to its own approved NDA. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially

reduces the price of both generic drugs and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

45. In its study, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when faced with competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes the price of both generic drugs to decrease.

46. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers such as Plaintiffs and their assignors benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

47. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drug at the same intervals and at the same rate at which they raised the price of the drug prior to generic entry.

48. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and given the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay its generic product. Such non-competition agreements deprive drug purchasers such as Plaintiffs of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

V. DEFENDANTS' ANTICOMPETITIVE SCHEME

A. Kos's Development and Introduction of Niaspan

49. Niacin is vitamin B3. It was discovered in the late 1800s, appears naturally in many foods, and was introduced as a dietary supplement in the United States in the 1930s. In proper dosages, niacin will raise levels of HDL cholesterol ("good" cholesterol) in patients. However, at high levels, niacin may cause a patient's skin to flush with redness and pose a risk of liver toxicity.

50. In the 1990s, Kos set out to develop a time-release version of niacin, which could (a) be marketed as a once-a-day therapy to boost HDL cholesterol in patients who needed treatment for cholesterol levels, and (b) avoid the side effects associated with high dosages of niacin. Eventually, Kos developed Niaspan, a time-release niacin product that it intended to market as a brand name prescription drug. Importantly, Kos did not claim to have discovered that niacin reduces cholesterol (a fact that was documented in the 1950s) or to be the first company to have developed a sustained release niacin formulation. Kos simply created a formulation that had a release rate that it claimed minimized or avoided certain side effects.

51. Kos was unable to patent the active ingredient in Niaspan because niacin was in the public domain. However, it sought and received seven patents to cover the formulation and use of Niaspan: Patent No. 6,080,428 (the '428 Patent); Patent No. 6,129,930 (the '930 Patent); Patent No. 6,406,715 (the '715 Patent); Patent No. 6,469,035 (the '035 Patent); Patent No. 6,676,967 (the '967 Patent); Patent No. 6,746,691 (the '691 Patent); and Patent No. 6,818,229 (the '229 Patent). Kos also purchased two additional patents: Patent Nos. 5,126,145 and 5,268,181 (the '145 Patent and the '181 Patent).

52. Kos filed an NDA for Niaspan, and, on July 28, 1997, it received FDA approval to market Niaspan for the treatment of mixed lipid disorders.

53. Over time, Kos submitted all nine of the above patents to the FDA for listing in the Orange Book.

54. In September of 1997, Kos began selling Niaspan. It eventually introduced Niaspan in dosages of 500 mg, 750 mg, and 1000 mg. Niaspan was the only once-a-day prescription formulation of extended-release niacin available for treating mixed lipid disorders. Because of its unique position, doctors prescribed Niaspan often, and the drug garnered hundreds of millions of dollars in annual sales.

55. Initially, sales of Niaspan made up the vast majority of Kos's sales revenue because Kos had no other significant drugs in its portfolio. As time went on, Kos began to sell other drugs, but Niaspan always accounted for a substantial portion of Kos's sales revenues:

a. In 2001, Kos sold $87 million of Niaspan -- 100% of the company's sales revenue for the year.

b. In 2002, Kos sold $146 million of Niaspan -- 84% of the company's sales revenue for the year.

c. In 2003, Kos sold $226 million of Niaspan -- 77% of the company's sales revenue for the year.

d. In 2004, Kos sold $319 million of Niaspan -- 64% of the company's sales revenue for the year.

e. In 2005, Kos sold $435 million of Niaspan -- 57% of the company's sales revenue for the year.

56. Kos (and later Abbott and AbbVie) had market power with respect to Niaspan. Indeed, on several occasions, Kos reported that it was able to raise prices on Niaspan (even though costs were not increasing) while simultaneously increasing its sales volumes on the drug.

B. Barr's Competitive Threat to Niaspan

57. After conducting extensive research and analysis regarding the patents that Kos had registered, Barr concluded that Kos's patents were invalid or unenforceable and/or that Barr's generic product would not infringe the patents. Barr spent over $2.3 million on this legal due diligence concerning the potential infringement or invalidity of Kos's patents. On October 2, 2001, Barr submitted ANDA 76-250 to the FDA, seeking approval to market a generic equivalent of the 1000 mg dosage of Niaspan.

58. On January 15, 2002, Barr sent Kos a Paragraph IV certification with respect to the listed patents covering Niaspan in a 1000 mg dosage. In that Paragraph IV certification, Barr stated that its proposed extended-release niacin, a generic version of Niaspan, would not infringe any of Kos's patents then listed in the Orange Book, that Kos's patents were invalid, and/or that Kos's patents were unenforceable. Barr was the first company to file such a certification. As the first ANDA filer to make a Paragraph IV certification, Barr expected to be entitled to a 180-day period of exclusivity (as against other generic manufacturers) to market its generic extended-release niacin once the FDA approved its ANDA.

59. Kos immediately saw Barr as a competitive threat, and sought to thwart Barr's efforts to bring generic Niaspan to market. President and CEO Adrian Adams promised that Kos

would "vigorously enforce [its] patent rights in order to protect Kos's cholesterol products, which [Kos has] effectively pioneered entirely on [its] own."

60. On March 4, 2002, Kos sued Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-1683), alleging that Barr's proposed generic extended-release niacin and related Paragraph IV certification infringed upon the '428 Patent and the '930 Patent with respect to the 1000 mg dosage of Niaspan. By operation of law, the filing of that lawsuit triggered a thirty-month stay that prohibited the FDA from granting final approval to Barr to launch a generic equivalent of Niaspan.

61. In the months that followed, Kos filed two more patent infringement lawsuits against Barr relating to Niaspan.

62. On August 13, 2002, Kos filed a second patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-6409), alleging that Barr infringed the '428 Patent and '930 Patent by filing ANDA 76-738 (with an accompanying Paragraph IV certification) with respect to the 500 mg and 750 mg dosages of Niaspan.

63. On November 12, 2002, Kos filed a third patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 02-cv-8995), alleging that Barr infringed the '715 Patent by submitting a supplemental Paragraph IV certification (dated September 30, 2002) regarding Niaspan.

64. Those cases were all consolidated into one proceeding. Under the law as it existed at that time, each of those lawsuits triggered a new thirty-month stay, and the last of those thirty-month stays began to run on September 30, 2002 (the date of Barr's supplemental Paragraph IV certification). Thus, the FDA was stayed from granting Barr final approval for marketing any generic equivalent of Niaspan until March 31, 2005.

65. On March 26, 2004, Kos filed a fourth patent infringement lawsuit against Barr in the United States District Court for the Southern District of New York (docketed as 04-cv-1683), alleging that Barr infringed the '967 Patent by filing Paragraph IV certifications with respect to Niaspan.

66. This fourth case was consolidated with the first three cases. In the consolidated proceeding, Barr filed counterclaims against Kos, seeking declaratory judgments that Barr's Paragraph IV certifications did not infringe any of the relevant patents held by Kos. Barr's counterclaims also sought rulings that those patents were invalid or otherwise unenforceable.

67. On September 3, 2004, Barr filed an action against Kos in the United States District Court for the Southern District of New York (docketed as 04-cv-7086), seeking a declaratory judgment that Barr was not infringing the '691 Patent and/or that the '691 Patent was invalid or otherwise unenforceable. This fifth lawsuit was also consolidated with the other pending patent infringement actions.

68. While the patent suits were pending, and while the thirty-month stay was still in place from the first three lawsuits, the FDA granted tentative approval to Barr's ANDA. Barr received tentative approval for its 1000 mg product on May 9, 2003 and received tentative approval for its 500 mg and 750 mg products on June 13, 2003. Barr expected to receive final approval from the FDA shortly after the last of the thirty-month stays expired -- that is, shortly after March 31, 2005. (Unless indicated otherwise, "Niaspan" or "extended-release niacin" refers to all of the strengths of the drug.)

69. The patent lawsuits continued for more than two years without any substantive rulings on the merits of the patent claims. The court issued no claim construction rulings and no summary judgment rulings. On December 3, 2004, the court scheduled the consolidated cases for trial in January of 2006.

C. Barr's Preparations to Launch Generic Niaspan At-Risk

70. As 2004 was drawing to a close, Barr was preparing to launch generic extended-release niacin "at-risk." It planned to launch shortly after the thirty-month stay expired, but before the patent litigation was resolved. Launching before resolution of the patent infringement litigation is considered "at-risk" because the generic manufacturer faces the risk of substantial damages if the patent litigation results in a favorable ruling for the brand name manufacturer. A generic manufacturer that attempts an at-risk launch must therefore be confident of eventually prevailing in its patent case.

71. By the spring of 2005, Barr was ready, willing, and able to launch its generic extended-release niacin as soon as the FDA approved Barr's ANDA. Reports concerning Barr's anticipated at-risk launch caused Kos's shares to drop 13% in December of 2004.

72. Barr's at-risk launch would have brought generic Niaspan to market in the spring of 2005, without regard to the strength of the claims in the pending patent lawsuits, and without regard to the expiration dates on any of Kos's patents. Had Barr launched at that time, Barr would have had the benefit of its 180-day exclusivity period, free from competition from other generic manufacturers.

73. Kos saw Barr's impending at-risk launch as a serious competitive threat to which it swiftly responded.

74. Kos began preparing to launch its own authorized generic version of Niaspan, that would have (a) effectively deprived Barr of its 180 days of exclusivity as the sole generic on the market, and (b) replaced some of Kos's lost brand revenues with those from authorized generic sales. Kos began manufacturing an authorized generic version of Niaspan to have inventory on hand to sell as soon as Barr launched at-risk. By the end of the first quarter of 2005, Kos had accumulated substantial inventory for its authorized generic launch. Kos was prepared to launch,

and would have launched, an authorized generic version of Niaspan in early 2005 if Barr had launched its generic extended-release niacin product at-risk.

75. On March 7, 2005, Kos sought a preliminary injunction to prohibit Barr from proceeding with its at-risk launch of generic Niaspan. The court held a hearing on Kos's application for a preliminary injunction on March 18, 2005.

76. At the time of the March 18th hearing, Barr was ready to launch its generic Niaspan and was accumulating the inventory that would be required to fill orders for its generic product once the launch occurred. Barr was waiting only for the FDA to issue final approval, which Barr expected to receive in April 2005.

77. However, both Kos and Barr had enormous incentives to settle the patent infringement litigation and avoid competition. Niaspan constituted the vast majority of Kos's company-wide sales revenue from 2001 through 2005; losing a substantial portion of that revenue stream -- as Kos would have if the patents were held by a court to be invalid, unenforceable, or not-infringed -- would have drastically affected Kos's profits. And without a substantial revenue stream from Niaspan, Abbott would have paid vastly less for Kos the next year. Kos, therefore, was desperate to settle the patent litigation with Barr. Even Barr acknowledged that the patent infringement litigation "was literally 'bet-the-company' for Kos because Niaspan provided over 80 percent of the company's profits to support its $1.8 billion market capitalization."

78. Barr also desired to settle the patent litigation. If Kos launched an authorized generic as it planned to do, Barr's profits during its 180-day exclusivity period would have been much lower than if Barr were the sole source for generic Niaspan. The competition among multiple generics would have driven down the price of generic Niaspan. Once there are multiple generic versions of the same brand drug available, the generic behaves like a commodity, with

little to distinguish one generic from another except price. While such competitive generic sales are still profitable, it can be substantially more profitable to be paid by the brand company not to compete. Barr knew that, rather than entering the market and competing, it could make more profit by agreeing to delay entry in exchange for a portion of Kos's monopoly profits from Niaspan, paid in the form of an Exclusion Payment.

D. Kos's Reverse Payment to Barr

79. On March 30, 2005, before the court issued a ruling on Kos's application for a preliminary injunction, Kos and Barr announced that they had "settled" the patent litigation and asked the court to postpone any ruling on that application so that they could formalize their settlement. The court issued a Conditional Order of Discontinuance on March 30, 2005.

80. In March of 2005, Kos agreed to pay Barr (the purported infringer) to settle the patent litigation and delay the introduction of generic Niaspan. Kos paid Barr because Barr intended to launch in April of 2005, and Niaspan was too important to Kos for it to risk the possibility of an at-risk generic launch by Barr. Barr's launch would have severely impacted Kos's sales of Niaspan, affected its valuation, and even threatened its viability as a company. Kos needed to prevent generic entry so that it could continue to charge high prices and sell high volumes of Niaspan.

81. By paying Barr, Kos used the strength of its wallet as opposed to the strength of its patents to obtain Barr's agreement not to launch generic Niaspan. Recognizing the substantial likelihood that its Niaspan patents would be invalidated and/or that the generics' products would be adjudged non-infringing, Kos agreed to share its monopoly rents with Barr as the *quid pro quo* for Barr's agreement not to compete with Kos by selling generic Niaspan until September 20, 2013.

82. Under the agreement not to compete (the "Exclusion Payment Agreement"), Kos agreed to make continuing substantial payments to Barr over a period of eight years. In return for those payments, Barr agreed to refrain from launching a generic equivalent of Niaspan until September 2013. That agreement preserved Niaspan's dominant position in the market, while sharing some of the supracompetitive revenues resulting from that dominant position. Kos and Barr attempted to disguise the payments as compensation to Barr for services that it was to provide under contemporaneous supply and promotion agreements. However, the payments to Barr (and later Teva) far exceeded the fair value of any services that Barr was to provide under those agreements. Indeed, Kos did not need Barr to provide any of the services provided under these agreements. The real purpose for making the payments was to induce Barr (and later Teva) to agree to delay the date on which it would begin competing with Kos's branded Niaspan.

83. On April 12, 2005, Kos and Barr simultaneously executed the following three contracts that were explicitly linked and together set out the terms of the Exclusion Payment Agreement:

a. **Settlement and Licensing Agreement.** Kos and Barr agreed to drop all claims and counterclaims pending against each other in the patent lawsuits. Kos gave Barr a license for all of the patents arguably covering Niaspan on the condition that Barr would not bring a generic equivalent of Niaspan to market until September 20, 2013 (or such earlier time as may be required to preserve Barr's right to market a generic exclusively for 180 days). Kos also agreed that it would not launch an authorized generic version of Niaspan after Barr ultimately entered the market with generic extended-release niacin. It would have made economic sense for Kos to launch an authorized generic and Kos had been planning to do so before this agreement, but such a launch would have severely impacted the profits that Barr could have earned from selling generic Niaspan. Finally, Barr explicitly agreed that it would not launch generic Niaspan until September 20, 2013.

b. **Co-Promotion Agreement.** For as long as Barr kept its generic Niaspan off the market, as provided in the Settlement and Licensing Agreement, Kos agreed to pay Barr (through Duramed and DPSC, two Barr subsidiaries, which later became Teva Women's Health, Inc.) a royalty on all of Kos's sales of Niaspan and Advicor, another Kos drug. Barr, Duramed, and DPSC agreed to promote Niaspan and Advicor to obstetricians, gynecologists, and other doctors

specializing in women's health. The royalty that Kos agreed to pay to Barr was to be based upon overall sales of Niaspan and Advicor, regardless of whether the sales were generated by Barr's sales force, and provided another incentive for Barr not to disrupt brand Niaspan sales.

c. **License and Manufacturing Agreement.** Kos (and its subsidiary, Kos Life Sciences Inc.) made a non-refundable lump-sum payment to Barr, ostensibly as compensation for Barr's investment in developing FDA-approved manufacturing processes for Niaspan and Advicor. Kos (and Kos Life Sciences Inc.) also agreed to make quarterly payments to Barr for every quarter that Barr remained ready to manufacturer Niaspan and Advicor. Barr agreed to serve as a ready back-up supplier to Kos for those products, and agreed to sell them to Kos at an agreed-upon contract price. If Barr sold a generic equivalent of Niaspan to any third-party before September 20, 2013, Kos would have no further obligation to make quarterly payments to Barr.

84. The Exclusion Payment Agreement had two other notable provisions:

a. Kos and Barr agreed to do all things reasonably necessary to further the intent and purposes of the transactions contemplated by the Agreement; and

b. Kos and Barr agreed that either company could transfer its rights and obligations to a successor entity through a merger or other corporate takeover.

85. On April 12, 2005, as envisioned by the Exclusion Payment Agreement, the patent court dismissed all of the patent infringement cases pending between Barr and Kos regarding Niaspan.

86. Under the Exclusion Payment Agreement, Kos (and its successors) paid Barr (and later Teva) to withhold generic Niaspan from the market until 2013. The payments were substantial and included the following:

a. An "upfront fee" believed to be approximately $5 million purportedly paid to compensate Barr for being ready to manufacture Niaspan and Advicor under the License and Manufacturing Agreement that has far exceeded the value that Barr (and later Teva) provided to Kos (and its successors) by being ready to manufacture and supply Niaspan.

b. Additional quarterly payments, purportedly paid to compensate Barr (and later Teva) for remaining ready to manufacture Niaspan and Advicor under the License and Manufacturing Agreement, that far exceeded the value that Barr (and later Teva) provided by remaining ready to manufacture and supply Niaspan and Advicor.

c. Hundreds of millions of dollars in value transferred from Kos to Barr (and later Teva) as a result of the agreement by Kos (and its successors) not to launch an authorized generic version of Niaspan during Barr's (and later Teva's) 180-days of exclusivity, which began on September 20, 2013, notwithstanding the facts that:

i. Kos had been planning to launch an authorized generic when faced with Barr's impending at-risk launch in 2005; and

ii. It made economic sense for AbbVie to launch an authorized generic during Teva's 180-day exclusivity period to (1) retain some of the sales that Teva's less expensive generic sought to capture, and (2) thereby preserve profits lost as a result of Teva's generic entry.

d. Quarterly royalty payments, purportedly to compensate Barr (and later Teva) for promoting Niaspan and Advicor. These payments totaled $45 million in 2006 and $37 million in 2007, the maximum provided under the copromotion agreement, and on information and belief continued in subsequent years. These payments were not legitimately tethered to and far exceeded the value of the promotion efforts that Barr (and later Teva) provided.

e. Tens of millions of dollars in value transferred from Kos to Barr as a result of Kos's agreement to grant an exclusive license to Barr to sell Advicor beginning September 2013, and thereby refrain from launching an authorized generic Advicor notwithstanding the fact that it made economic sense for AbbVie to launch an authorized generic to (1) retain some of the sales that Barr's (and later Teva's) less expensive generic sought to capture, and (2) thereby preserve profits lost as a result of Barr's/Teva's generic entry.

87. All of these benefits had substantial value to Barr, and Barr could not have obtained any of them if it had litigated and won the patent case. These payments caused Barr to agree to stay out of the market far longer than it would have agreed to in a payment-free settlement based solely on the strength of Kos's patent claims. Kos made these payments to compensate Barr for agreeing to delay its entry into the market.

88. In the years following execution of the Exclusion Payment Agreement, Barr (and later Teva) continued to receive those payments, and Barr (and later Teva) continued to honor the commitment not to launch generic Niaspan until September 20, 2013, more than eight years later.

89. Kos and Barr knew and intended that the Exclusion Payment Agreement would prevent other generic companies from launching their own generic Niaspan before Barr, and that it would thereby create a bottleneck. As the first filer of an ANDA for a generic extended-release niacin, Barr/Teva is entitled to market its generic Niaspan for 180 days free from competition from other generic manufacturers. The operation of the parties' Exclusion Payment Agreement blocked any other generic Niaspan products from coming to market until 180 days after September 20, 2013. In the absence of a forfeiture event, the FDA would not approve any subsequently-filed ANDAs until the first-filer's exclusivity period had run, which would not occur until 180 days after Barr/Teva's actual launch.

90. But for the Exclusion Payment Agreement and the parties' ongoing adherence to and performance under that Agreement, generic competition for Niaspan would have occurred earlier and prices for both brand name Niaspan and generic extended-release niacin would have been lower. Specifically, Barr/Teva would have begun selling a less expensive AB-rated version of Niaspan sometime before September 20, 2013 by: (i) launching at risk following FDA approval after the expiration of the 30-month stay; (ii) prevailing in the patent litigation; or (iii) entering into a settlement that did not include a large and unjustified payment. In addition, when Barr/Teva began selling generic Niaspan, Kos/Abbott/AbbVie would have begun selling its own less expensive authorized generic version of Niaspan in direct competition with the Barr/Teva generic, and, 181 days after Barr/Teva's launch, other generic manufacturers would have been able to launch their own generic Niaspan products.

91. The purpose and effect of the Exclusion Payment Agreement was to suppress generic competition and to allow Kos/Abbott/AbbVie to charge supracompetitive prices for Niaspan without losing significant sales.

92. Consistent with the Exclusion Payment Agreement, Kos and Barr took steps to fraudulently conceal their unlawful agreement to suppress generic competition.[1]

93. When the Exclusion Payment Agreement was announced, both Kos and Barr repeatedly stated that the effect of the agreement was to bring a generic equivalent of Niaspan to the market in 2013, which they asserted was four years earlier than the expiration date of the last of Kos's patents ostensibly covering Niaspan. These statements were false and misleading -- and both companies knew that they were false and misleading. The statements ignored the fact that Barr would have launched a generic equivalent of Niaspan at-risk in April of 2005. Thus, when Kos and Barr proclaimed that the Exclusion Payment Agreement would bring generic equivalents of Niaspan to market sooner than they otherwise would have arrived, both companies knew that the real purpose and effect of the Exclusion Payment Agreement was to delay generic entry for many years.

94. When the Exclusion Payment Agreement was announced, Kos and Barr both refused to disclose the amount of the payments provided under the Agreement, because they had agreed to conceal the amounts of the payments that Barr was receiving. Repeatedly, when Wall Street analysts asked either company to disclose the amounts of the payments (or even the details for how the amounts would be calculated), the companies refused. Indeed, during conference calls with investment bank analysts, Kos representatives refused to answer direct questions from analysts in the financial community who asked about the financial terms of the payments that Kos was making to Barr (including an April 13, 2005 Conference Call, in which Barr's Chief Executive Officer Bruce Downey refused to provide details when asked about the financial terms

[1] The allegations in paragraphs 92-97 are included to preserve Plaintiffs' appellate rights. Plaintiffs understand that the Court has dismissed similar allegations of fraudulent concealment in other cases pending as part of MDL Docket No. 2460 and do not dispute that the Court would

of the Agreement, and an August 4, 2005 Conference Call, in which Kos's Interim Chief Financial Officer Juan Rodriguez refused to provide details of those financial terms).

95. Kos filed copies of contracts dated April 12, 2005 with the Securities and Exchange Commission as part of its 10-Q filing dated August 9, 2005, but the publicly-filed versions of those contracts redacted the financial terms regarding the payments. Neither company reported the amounts of the payments as separate items in their financial reports. Additionally, the publicly-filed versions of the contracts contained recital clauses that falsely stated that the parties were hastening the entry of generic Niaspan, when in fact the parties had agreed to delay generic entry for many years.

96. Because the alleged conspiracy was self-concealing and material facts were affirmatively concealed and misrepresented by Defendants and their co-conspirators, Plaintiffs had no knowledge of the alleged conspiracy, or of facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

97. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiffs' claims have been tolled until a date less than four years prior to the filing of the first class action on behalf of direct purchasers of Niaspan.

E. The FDA's Final Approval of Barr's Generic Niaspan

98. On April 26, 2005, shortly after the Exclusion Payment Agreement was signed and as Barr expected, the FDA granted final approval to Barr to manufacture and market generic Niaspan.

99. At the same time, as a result of the Exclusion Payment Agreement, Barr disposed of the inventory that it had accumulated to prepare for its generic launch and took an inventory write-down in connection with its decision not to launch in April of 2005. Kos did the same

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reach the same result in this case.

thing for its inventory of an authorized generic version of Niaspan. (Kos had accumulated that inventory prior to the Exclusion Payment Agreement, on the expectation that it would begin selling an authorized generic Niaspan product to compete with Barr's generic Niaspan product as soon as Barr launched).

F. Abbott's Acquisition of Kos and Continued Compliance with the Exclusion Payment Agreement

100. In November of 2006, Abbott proposed to acquire control of Kos through a tender offer transaction. Abbott offered to pay Kos shareholders $78 per share, a 56% premium on the open market share price of $50 per share. At the time of the offer, Kos's portfolio of products was still heavily dependent on Niaspan, and Kos had few products in development. Thus, Niaspan (and the unlawful and ongoing Exclusion Payment Agreement preventing generic competition to it) was a central element of Abbott's valuation of Kos's business. Had generic versions of Niaspan entered the market prior to November 2006, Abbott would not have been willing to pay nearly as much as it ultimately paid for Kos.

101. Abbott's tender offer was successful, and Kos was merged into Abbott in December of 2006. As Kos's successor, Abbott stepped into the shoes of Kos with respect to the ongoing unlawful Exclusion Payment Agreement with Barr. Barr continued to refrain from entering the market with a generic equivalent of Niaspan, staying off the market until the agreed upon launch date on September 20, 2013, and Abbott continued to make the agreed-upon payments to Barr. In this way, both parties continued with the unlawful Exclusion Payment Agreement that suppressed generic competition for Niaspan.

102. In addition to succeeding to Kos's liability, Abbott joined the ongoing unlawful course of conduct to suppress generic competition to Niaspan. Abbott did not withdraw from that conspiracy and instead continued to participate in and take affirmative steps to perpetuate it.

103. To the extent that the Exclusion Payment Agreement had any minimal value to Kos in the form of co-promotion services or backup supply arrangements, those considerations had even less value to Abbott; Abbott was a substantially larger enterprise than Kos, had an even larger promotion force, and had no use for additional supply capacity. The Exclusion Payment Agreement was valuable to Abbott because the Agreement was postponing Barr's launch of a generic equivalent of Niaspan, and Abbott was willing to continue to pay Barr for the ongoing suppression of generic competition.

104. Because it was substantially larger, Abbott was better able to exploit the market advantages created by the ongoing scheme to suppress generic competition. After Abbott took over the Niaspan business, sales of Niaspan increased significantly. Annual U.S. retail sales of Niaspan more than doubled between 2006 and 2012, from $474 million to $1.03 billion.

G. Teva's Acquisition of Barr and Continued Compliance with the Exclusion Payment Agreement

105. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva. Teva continued to comply with the Exclusion Payment Agreement. Teva continued to refrain from entering the market with generic Niaspan, agreeing to hold off until September 20, 2013, and Abbott continued to make the agreed-upon payments to Teva.

106. Because of the acquisition, Teva also owned (either directly or indirectly) Barr's first-filer rights. Accordingly, no other generic company was able to launch a generic equivalent of Niaspan until Teva's 180-day period as the exclusive seller of generic extended-release niacin expired. Following Teva's launch of a generic equivalent of Niaspan on September 20, 2013, no other generic manufacturer was permitted to introduce generic Niaspan until March 2014.

107. In addition to succeeding to Barr's liability, Teva joined the ongoing unlawful course of conduct and conspiracy to suppress generic competition to Niaspan. Teva did not withdraw from that conspiracy and instead continued to participate in it.

H. Abbott's Subsequent Actions to Preserve the Exclusion Payment Agreement

108. Between 2006 and 2012, Abbott took additional steps to ensure that nothing disrupted the Exclusion Payment Agreement or permitted generic competition for Niaspan to commence before September of 2013.

109. For example, Abbott knew that, if any other generic drug manufacturer obtained a final judgment following a court decision of invalidity, unenforceability, or non-infringement of the Niaspan patents, Teva's 180-day exclusivity period would begin to run. In such a case, the Exclusion Payment Agreement permitted Teva to launch its generic product immediately, before the agreed-upon launch date of September 20, 2013, cutting short Defendants' unlawful scheme. Recognizing this risk, Abbott acted aggressively to prevent such a disruption.

110. On March 6, 2009, Abbott filed a patent infringement lawsuit against Lupin Limited in the United States District Court for Delaware (docketed as 09-cv-152). Abbott alleged that Lupin, a generic manufacturer, had infringed Abbott's patents by filing a Paragraph IV certification as part of an effort to gain approval for and launch a generic Niaspan product. On June 13, 2012, Abbott and Lupin stipulated to a dismissal of the lawsuit. The court never ruled on whether Lupin had infringed Abbott's patents or issued any final judgment on Lupin's claims that Abbott's patents were invalid or unenforceable.

111. After March 2009, Abbott filed numerous additional patent infringement lawsuits against generic manufacturers that filed Paragraph IV certifications with respect to potential generic Niaspan products. Abbott (later AbbVie) settled seven of those cases and dismissed them by stipulation without any final judgments entered on the infringement, validity, or enforceability of any of Abbott/AbbVie's patents.

a. In *Abbott Laboratories* v. *Sun Pharmaceuticals Indus. Ltd.*, No. 10-CV-112 (D. Del.), the court scheduled trial for mid-2013 but the parties settled in February 2013, before the court issued any substantive rulings;

b. In *Abbott Laboratories* v. *Sandoz, Inc.*, No. 10-CV-538 (D. Del.), the parties settled in March 2013, one month before trial, and again before the court issued any substantive rulings;

c. In *Abbott Laboratories v. Amneal Pharmaceuticals LLC,* No. 12-CV-235 (D. Del.), the parties settled in March 2013, before the court issued any substantive rulings;

d. In *Abbott Laboratories v. Cadila Healthcare Ltd.*, No. 12-CV-0065 (D. Del.), the parties settled on August 14, 2013, before the court issued any substantive rulings;

e. In *Abbott Laboratories* v. *Kremers Urban Pharmaceuticals, Inc.*, No. 12-CV-703 (D. Del), the parties settled on September 26, 2013, before the court issued any substantive rulings;

f. In *Abbott Laboratories v. Watson Laboratories, Inc.*, No. 12-CV-324 (D. Del.), the parties settled on September 12, 2013, before the court issued any substantive rulings; and

g. In *Abbott Laboratories v. Mylan, Inc.*, No. 12-CV-257 (D. Del.), the parties settled on February 4, 2014, before the court issued any substantive rulings.

112. In pursuing and settling these lawsuits, Abbott/AbbVie has been able to avoid the entry of any final judgment that would have triggered Teva's 180-day exclusivity. Through delay and settlements, Abbott/AbbVie has ensured that no final judgment has been entered on non-infringement, invalidity, or unenforceability of the relevant patents.

113. Abbott/AbbVie has prosecuted these patent cases as part of its covenant in the Exclusion Payment Agreement to take steps necessary to preserve the agreement to suppress generic competition. Abbott/AbbVie's conduct in these lawsuits is part of and in furtherance of its ongoing unlawful agreement with Teva to suppress generic competition in the market for Niaspan.

I. AbbVie's Continuation of the Unlawful Agreement to Suppress Generic Competition

114. In 2012, Abbott announced that it was spinning off most of its prescription drug business into a new company, AbbVie. That spin-off became effective as of January 1, 2013. As Abbott's successor, AbbVie has stepped into the shoes of Abbott with respect to the ongoing

unlawful Exclusion Payment Agreement with Teva. Teva continued to refrain from launching a generic equivalent of Niaspan until September 20, 2013, and AbbVie continued to make the agreed-upon payments to Teva.

115. Upon the transition of the Niaspan business from Abbott to AbbVie on or about on January 1, 2013, AbbVie joined the ongoing unlawful course of conduct and conspiracy to suppress generic Niaspan competition. AbbVie did not withdraw from that conspiracy and instead continued to participate in it.

J. The Continuing Effects of the Unlawful Agreement to Suppress Generic Competition

116. Until September 20, 2013, no generic equivalent of Niaspan was on the market in the United States. When Teva finally began selling generic Niaspan, AbbVie adhered to its agreement not to launch an authorized generic. With only one generic product on the market, Plaintiffs were denied the lower prices that full generic competition would have brought to the market. This lack of full generic competition was the direct result of the ongoing unlawful Exclusion Payment Agreement (and the subsequent settlements with other generic competitors) that will continue to dampen competition at least through the end of 2015.

117. The unlawful agreement has resulted in higher prices for Teva's extended release niacin. Since September of 2013, when Teva began selling generic Niaspan, Teva has been able to charge higher prices than those it would have been able to charge but for AbbVie's promise not to launch an authorized generic of Niaspan. Thus, Teva has been able to launch and sell its generic at a higher price than it otherwise would have without competitive pressure from an authorized generic version of Niaspan during the most lucrative time immediately following Teva's launch.

118. During the entire four-year period preceding the filing of the first direct purchaser class complaint, Defendants' unlawful conduct and violation of the antitrust laws continued, Abbott and AbbVie made payments to Teva to compensate it for refraining from entering the market with generic Niaspan prior to September 20, 2013, and Plaintiffs (or their assignors) suffered injury from every purchase made on each day that Defendants' unlawful Exclusion Payment Agreement not to compete remained in place. During the applicable limitations period, Defendants operated under an ongoing Exclusion Payment Agreement to suppress generic competition, and Plaintiffs and/or their assignors were injured by Defendants' ongoing conduct.

K. Injury to Competition and Plaintiffs' Damages

119. On May 9, 2003, the FDA issued a tentative approval of Barr's ANDA for a generic equivalent of the 1000 mg strength of Niaspan. On June 13, 2003, the FDA issued a tentative approval of Barr's ANDA for a generic equivalent of the 500 mg and 750 mg strengths of Niaspan. The FDA issues tentative approval only when it determines that an ANDA would otherwise be ready for final approval but for a thirty-month stay.

120. But for Defendants' overarching, anticompetitive, and ongoing scheme to delay generic Niaspan competition in the United States, generic Niaspan would have been available in the United States far earlier than September 20, 2013, the first date that generic Niaspan actually became available.

121. Additionally, but for the illegal conduct described in the complaint, Kos would have launched its own authorized generic Niaspan product at the same time that Barr launched its extended-release niacin, resulting in additional price competition for Niaspan and its generic equivalents during Barr's 180-day exclusivity period.

122. But for the anticompetitive and illegal conduct alleged in this complaint, Plaintiffs and their assignors would have saved hundreds of millions of dollars on their purchases of extended-release niacin.

123. The active ingredient in Niaspan is extended-release niacin. Its pharmacological profile, and thus its side effect and efficacy profile, are different from other prescription and nonprescription medicines that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Niaspan, cannot be automatically substituted for Niaspan by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Niaspan, and thus are not economic substitutes for, nor reasonably interchangeable with, Niaspan.

124. Defendants' unlawful Exclusion Payment Agreement was designed to and did in fact: (a) preclude the entry of less expensive generic versions of extended-release niacin in the United States; (b) fix, raise, maintain or stabilize the prices of extended-release niacin products; (c) permit Kos/Abbott/AbbVie to maintain a monopoly in the United States for extended-release niacin; (d) allocate 100% of the United States extended-release niacin market to Kos/Abbott/AbbVie until September 20, 2013; and (e) allocate 100% of the United States generic extended-release niacin market to Barr/Teva for six months beginning on September 20, 2013 .

125. Defendants violated sections 1 and 2 of the Sherman Act through their conspiracy to improperly maintain and extend their market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of extended-release niacin.

VI. ANTICOMPETITIVE EFFECTS OF DEFENDANTS' SCHEME

126. Defendants' scheme and payments to suppress generic competition to Niaspan significantly delayed the sale of generic Niaspan. But for Defendants' unlawful conduct, Barr/Teva would have begun selling a generic version of Niaspan well before September 20, 2013 by: (i) launching at risk following FDA approval after the expiration of the 30-month stay; (ii) prevailing in the patent litigation; or (iii) entering into a settlement that did not include a large and unjustified payment. In addition, when Barr/Teva began selling generic Niaspan, Kos/Abbott/AbbVie would have begun selling its own less expensive authorized generic version of Niaspan in direct competition with the Barr/Teva generic, and, 181 days after Barr/Teva's launch, other generic manufacturers would have been able to launch their own generic Niaspan products.

127. The generic manufacturers seeking to sell generic Niaspan have extensive experience in the pharmaceutical industry, including in obtaining approvals for ANDAs, marketing generic pharmaceutical products, manufacturing commercial quantities adequate to meet market demand, and, where appropriate, entering into arrangements with other generic manufacturers to waive or relinquish 180-day exclusivity in order to bring generic drugs to market in a timely manner.

128. Defendants' unlawful conduct has delayed the sale of generic Niaspan in the United States, and unlawfully enabled Kos/Abbott/AbbVie to sell Niaspan at artificially inflated, supracompetitive prices without losing sales to generic competitors. Defendants' conduct also allowed Teva to sell generic Niaspan at artificially inflated prices because of the absence of competition from an authorized generic.

129. As a consequence, Plaintiffs and/or their assignors have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

VII. INTERSTATE COMMERCE

130. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VIII. MARKET POWER AND MARKET DEFINITION

131. At all relevant times, Kos/Abbott/AbbVie had market power with respect to extended-release niacin because it had the power to raise and/or maintain the price of the drug at supracompetitive levels without losing substantial sales.

132. A small but significant, non-transitory price increase above the competitive level for Niaspan by Kos/Abbott/AbbVie would not have caused a significant loss of sales sufficient to make the price increase unprofitable.

133. At competitive price levels, Niaspan does not exhibit significant, positive cross-elasticity of demand with respect to any product other than AB-rated generic versions of Niaspan.

134. The 2011 AIM-HIGH study published in the New England Journal of Medicine found that extended-release niacin did not prevent heart attacks in patients whose cholesterol was controlled with a statin. This negative published study resulted in a significant decline in demand for Niaspan. However, Abbott and AbbVie were able to offset the decline in demand by raising the price of Niaspan approximately 37% without experiencing any additional loss in sales -- something they could not if they did not have monopoly power.

135. For clinical reasons, among others, physicians and patients prefer Niaspan to other products designed to treat lipid disorders.

136. The existence of other products designed to treat similar disorders has not significantly constrained Kos/Abbott/AbbVie's pricing of Niaspan. At all relevant times, Kos/Abbott/AbbVie's price for Niaspan has been substantially above its marginal cost of production, and substantially above its marginal cost including marketing costs. Kos/Abbott/AbbVie has never lowered the price of Niaspan in response to the pricing of other cholesterol treatments (or the launch of generic versions of those other treatments).

137. Kos/Abbott/AbbVie needed to control only Niaspan and its AB-rated generic equivalents, and no other products, in order to maintain the price of Niaspan profitably at supracompetitive prices. Only the market entry of an AB-rated generic Niaspan caused Kos/Abbott/AbbVie to lose sales of Niaspan at supracompetitive prices.

138. Kos/Abbott/AbbVie knew that entry of a generic version of Niaspan would be a uniquely significant market event. The entry of other branded drugs in the same therapeutic class (or generic versions of those other brands) did not take substantial sales from Niaspan or cause Kos/Abbott/AbbVie to lower its price. But Kos/Abbott/AbbVie predicted that entry of generic Niaspan would immediately cause branded Niaspan to lose well more than half of its unit sales. Likewise, Barr estimated that its generic version of Niaspan would take essentially all of its sales from branded Niaspan and few if any sales from other branded drugs (or generic versions of those other brands).

139. At all relevant times, Kos/Abbott/AbbVie has sold Niaspan at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

140. Kos/Abbott/AbbVie had, and exercised, the power to exclude and restrict competition in the market for Niaspan and its AB-rated generic equivalents.

141. Kos/Abbott/AbbVie at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

142. To the extent that Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is extended-release *niacin* (*i.e.*, Niaspan and its AB-rated generic equivalents). During the relevant time, Kos/Abbott/AbbVie has been able to profitably maintain the price of extended-release niacin well above competitive levels.

143. The relevant geographic market is the United States and its territories

144. Until September 2013, Kos/Abbott/AbbVie's market share in the relevant market was 100%, implying a substantial amount of market power.

IX. EFFECTS ON COMPETITION AND INJURY TO PLAINTIFFS

145. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Niaspan from generic competition.

146. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Niaspan, has caused Plaintiffs and/or their assignors to pay more than they would have paid for extended-release niacin absent Defendants' illegal conduct.

147. But for Defendants' anticompetitive conduct, Plaintiffs and/or their assignors would have paid less for extended-release niacin by: (a) substituting purchases of less-expensive AB-rated generic Niaspan for their purchases of more-expensive branded Niaspan; and (b) purchasing generic Niaspan at lower prices sooner.

148. Plaintiffs and/or their assignors purchased substantial amounts of Niaspan. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and/or their assignors were compelled to pay, and did pay, artificially inflated prices for extended-release niacin. Plaintiffs and/or their assignors paid prices for extended-release niacin that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein.

149. Plaintiffs' injuries are injuries of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' acts unlawful.

150. Defendants' unlawful conduct threatens continuing loss and injury to Plaintiffs unless enjoined by this Court.

X. CLAIMS FOR RELIEF

CLAIM I: Violation of 15 U.S.C. § 2 Monopolization (Overall Scheme) (Asserted against Abbott/AbbVie)

151. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 150 above as though fully set forth herein. This claim is asserted against Defendants Abbott and AbbVie.

152. At all relevant times, Kos/Abbott/AbbVie possessed substantial market power *(i.e.*, monopoly power) in the relevant market. Kos/Abbott/AbbVie possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

153. Through its overarching anticompetitive scheme, as alleged above, Kos/Abbott/AbbVie willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of a superior product, greater business acumen, or historic accident, and thereby injured Plaintiffs. Such conduct includes entering into the unlawful Exclusion Payment Agreement with Barr and continuing to adhere to that

Agreement thereafter. Kos/Abbott/AbbVie's conduct was designed to delay the introduction of generic Niaspan.

154. It was Kos/Abbott/AbbVie's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

155. Kos/Abbott/AbbVie's scheme harmed competition.

156. There is and was no cognizable, non-pretextual procompetitive justification for Kos/Abbott/AbbVie's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Kos/Abbott/AbbVie were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

157. As a direct and proximate result of Kos/Abbott/AbbVie's illegal and monopolistic conduct, as alleged herein, Plaintiffs and/or their assignors suffered injury to their business and property.

CLAIM II: Violation of 15 U.S.C. § 2
Attempt to Monopolize
(Asserted Against Abbott/AbbVie)

158. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 150 above as though fully set forth herein. This claim is asserted against Defendants Abbott and AbbVie.

159. Kos/Abbott/AbbVie, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Kos/Abbott/AbbVie's conscious objective to control prices and/or to exclude competition in the relevant market.

160. The natural and probable consequence of Kos/Abbott/AbbVie's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

161. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Kos/Abbott/AbbVie would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

162. As a direct and proximate result of Kos/Abbott/AbbVie's illegal and monopolistic conduct, Plaintiffs and/or their assignors suffered injury to their business and property.

CLAIM III: Violation of 15 U.S.C. § 1
Conspiracy in Restraint of Trade
(Asserted Against All Defendants)

163. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 150 above as though fully set forth herein.

164. The Exclusion Payment Agreement between Kos/Abbott/AbbVie and Barr/Teva involved: (a) a large and unjustified payment from Kos/Abbott/AbbVie to Barr/Teva; and (b) an agreement by Barr/Teva to delay marketing its generic Niaspan until September 20, 2013 (or earlier in certain circumstances). The payments from Kos/Abbott/AbbVie to Barr/Teva under the Agreement were the *quid pro quo* for Barr/Teva's agreement to delay marketing its generic version of Niaspan for many years. Absent the payments, Barr/Teva would not have agreed to delay marketing its generic version of Niaspan until 2013. In addition, the Exclusion Payment Agreement is a *per se* unlawful horizontal market allocation agreement that divides the relevant market temporally rather than geographically.

165. The purpose and effect of the unlawful Exclusion Payment Agreement was to allocate 100% of the United States market for extended-release niacin to Kos/Abbott/AbbVie; delay the sales of generic Niaspan products for up to eight years; allocate 100% of the United States market for generic extended-release niacin to Barr/Teva for six months after Barr/Teva

ultimately launched generic Niacin; and fix the price which Plaintiffs and/or their assignors paid for extended-release niacin at the higher, branded price.

166. The Exclusion Payment Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The Exclusion Payment Agreement is both a reverse-payment settlement agreement and a *per se* unlawful horizontal market allocation. The purpose and effect of the payments flowing from Kos/Abbott/AbbVie to Barr/Teva under the Exclusion Payment Agreement was to delay generic competition to Niaspan and there is no legitimate, nonpretextual, procompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

167. At all relevant times, Kos/Abbott/AbbVie possessed market power in the relevant market. Kos/Abbott/AbbVie possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

168. The goal, purpose and/or effect of the Exclusion Payment Agreement was to prevent and/or delay generic Niaspan and enable Kos/Abbott/AbbVie to continue charging supracompetitive prices for Niaspan without a substantial loss of sales. By means of the Kos/Abbott/AbbVie's payment to Barr/Teva, Defendants shared the supracompetitive profits that their unlawful agreement made possible.

169. As a direct and proximate result of Defendants' unlawful conspiracy in restraint of trade, Plaintiffs and/or their assignors have suffered injury to their business and property.

CLAIM IV: Violation of 15 U.S.C. § 1
Conspiracy to Monopolize
(Asserted Against All Defendants)

170. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 150 above as though fully set forth herein.

171. At all relevant times, Kos/Abbott/AbbVie possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Kos/Abbott/AbbVie possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

172. Through the Exclusion Payment Agreement with Barr/Teva, Kos/Abbott/AbbVie conspired with Barr/Teva to maintain monopoly power in the relevant market by preventing and delaying the entry of a competing AB-rated generic version of Niaspan. The unlawful Exclusion Payment Agreement allocated all sales of extended-release niacin in the United States to Kos/Abbott/AbbVie; delayed the sale of less expensive generic extended-release niacin; allocated all sales of generic extended-release niacin in the United States to Barr/Teva for six months after Barr/Teva ultimately launched generic Niaspan; and fixed the price at which Plaintiffs would purchase extended-release niacin at the higher, brand-name price.

173. The goal, purpose and effect of the Exclusion Payment Agreement was to maintain Kos's monopoly power in the United States for extended-release niacin in violation of section 2 of the Sherman Act, 15 U.S.C. § 2. The Exclusion Payment Agreement prevented and delayed generic Niaspan and enabled Kos/Abbott/AbbVie to continue charging supracompetitive prices for Niaspan without a substantial loss of sales.

174. Kos and Barr knowingly and intentionally conspired to maintain Kos's monopoly power in the relevant market.

175. Kos and Barr specifically intended that the Exclusion Payment Agreement would maintain Kos's monopoly power in the relevant market, and injured Plaintiffs thereby.

176. Kos and Barr each committed numerous overt acts in furtherance of the conspiracy.

177. As a direct and proximate result of Defendants' conspiracy to monopolize, Plaintiffs and/or their assignors suffered injury to their business and property.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

a. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

b. A permanent injunction enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct;

c. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

d. An award Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

e. Such other and further relief as the Court deems just and proper.

XII. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: April 14, 2015

Respectfully submitted,

/s/ Barry L. Refsin
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